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REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

Claims 1, 2, 4-8 and 11-15 were rejected under 35 USC § 112, first paragraph, as lacking adequate enablement for the prophylaxis of rosacea and couperose. In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

At the bottom of page 2 of the final rejection, the Examiner states that “undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention.” In response, Applicants submit that this is not the appropriate standard, and efficacy need not be demonstrated. Instead, the test for satisfaction of the enablement requirement is whether a person skilled in the art could take the teachings in the application and combine them with his or her own level of knowledge, and be able to practice the full scope of the invention without undue experimentation.

The Examiner concedes that there is adequate enabling support for treatment of rosacea and couperose, which implies that the Examiner accepts the allegations in the specification that NO-synthase inhibitors are effective in treating rosacea and couperose. A person skilled in the art would have been reasonable in the expectation that NO-synthase inhibitors might also have been effective in preventing rosacea and couperose.

Further, it is well known in the art, for example, that rosacea is usually seen in adults, more often in fair-skinned people, and mostly in people who have a history of flushing or blushing more easily and more often than the average person. Accordingly, there are well known criteria by which persons skilled in the art could determine likely candidates for developing rosacea. A person having ordinary skill in the art, combining the teachings in the specification, and combining those teachings with the well known risk factors for developing rosacea, would have been reasonable to expect that administration of an effective amount of NO-synthase inhibitors to such persons might have been effective to prevent the development of rosacea.

Consequently, Applicants submit that the Examiner has not, in fact, provided a good enough reason to doubt the allegations in the specification. Accordingly, the enablement in the specification must be accepted. *In re Marzocchi et al.*, 169 USPQ 367, 369 (CCPA 1971). Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Claims 1-4, 7-11 and 14-16 were rejected under 35 USC § 102(b) as being anticipated by Giacomoni, WO 96/26711. In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

At the bottom of page 4 of the final rejection, the Examiner finds that “[w]hile reducing the skin irritant effect of certain pharmaceutical substances, the NO synthase inhibitors of Giacomoni will inherently treat rosacea (sic) as claimed in the instant claims.” This, of course, presumes that A) compositions containing the NO synthase inhibitors of Giacomoni are applied to skin suffering from rosacea or susceptible thereto, B) such compositions contain an amount of the NO synthase inhibitor effective to treat or prevent rosacea and C) the compositions are applied over a period of time effective to treat or prevent rosacea. While it is *possible* that Giacomoni’s compositions could have been formulated and applied under conditions meeting characteristics A)-C) above, this is *not necessarily* the case. Consequently, Giacomoni fails as an inherent anticipation.

Indeed, Applicants submit that the Examiner has not established a *prima facie* case of inherency. As pointed out by the Board of Patent Appeals and Interferences in *Ex parte Levy*, 17 USPQ2d 1461, 1463-1464 (BPAI 1990):

“[T]he initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests upon the Examiner. * * * In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic

necessarily flows from the teachings of the applied prior art. [Emphasis in original.]”

Applicants submit that the Examiner has not discharged this initial burden.

First, the Examiner has not established that it is *necessarily* the case that Giacomoni’s compositions would have been applied to skin suffering from or susceptible to rosacea. Attached for the Examiner’s consideration is an English-language translation of the Giacomoni reference. “[R]osaceous acne” is mentioned at the bottom of the seventh page of the translation as an “area” that may be treated by Giacomoni’s compositions, but this disorder is only one of a large number of disorders that are listed. Accordingly, this shows that rosacea was not necessarily treated by Giacomoni’s compositions. Further, none of Giacomoni’s specific examples appear to apply Giacomoni’s exemplified compositions to skin suffering from or susceptible to rosacea. Consequently, it is certainly *not necessarily* the case that Giacomoni’s compositions inherently treated rosacea or skin susceptible to rosacea.

Second, the Examiner has not established that Giacomoni’s compositions would *necessarily* have contained NO-synthase inhibitors in an amount effective to treat or prevent rosacea, or, if they contained an effective amount for such purposes, that Giacomoni’s compositions would *necessarily* have been applied to skin suffering from or susceptible to rosacea for a period of time effective to treat or prevent rosacea. It is certainly *not necessarily* the case that Giacomoni’s compositions inherently contained NO-synthase inhibitors in an amount effective to treat or prevent rosacea, or, if they contained an effective amount for such

purposes, that Giacomoni's compositions would *necessarily* have been applied to skin suffering from or susceptible to rosacea for a period of time effective to treat or prevent rosacea.

Further on both of these points, Applicants submit that *overlap* in these characteristics is insufficient. As the quote from *Levy* makes clear, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." Overlap establishes a *possibility* that a characteristic may have been selected, but does *not* establish that any embraced characteristic would *necessarily* have been selected. *See, for example, In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), for the proposition that inherency is not established by probabilities or possibilities, and the mere fact that a property may result from a given circumstances is not sufficient; instead it must be shown that such property *necessarily* inheres in the thing described in the reference.

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and withdraw this rejection. The Examiner apparently concedes that Giacomoni does not expressly teach that NO-synthase inhibitors are effective to treat or prevent rosacea. The Examiner has found this is inherently taught. However, it has been explained above why it is not necessarily the case that the teachings of Giacomoni taught treatment or prevention of rosacea by NO-synthase inhibitors. Consequently, Giacomoni fails as an inherent anticipation, and Applicants respectfully request an early notice that this rejection has been reconsidered and withdrawn.

Claims 5, 6, 12 and 13 were rejected under 35 USC § 103(a) as being obvious over Giacomoni in view of either Breton et al. ("Breton"), U.S. Patent No. 5,795,574, or Ptchelintsev et al. ("Ptchelintsev"), U.S. Patent No. 5,847,003. In response, Applicants point out that this rejection was premised on Giacomoni constituting an inherent anticipation of the main instant claims. However, this has been shown above not to be the case. Neither Breton nor Ptchelintsev overcomes any of the deficiencies in Giacomoni. Accordingly, Applicants submit that the combination of Giacomoni and Breton and Ptchelintsev does not make out a *prima facie* case of the obviousness of the instant claims. Consequently, Applicants also respectfully request an early notice that this rejection has been reconsidered and withdrawn.

Respectfully submitted,
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